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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,580	09/12/2005	Patricia Lynne Conway	BSWV-P01-008	3799
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FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,580

Applicant(s)

CONWAY, PATRICIA LYNNE

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the recitation of "with a" under (c) in claim 1. In claim 1, "o" is missing for the temperatures indicated.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group I, claims 1-2 and 4-15 on 3/16/07 is acknowledged.

Claims 1-2 and 4-15 are being considered on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-10 and 12-15 are rejected under 35 U.S.C. 101 because this claim reads on the organism per se which is found in nature and thus, is unpatentable to applicant.

Consequently, the claim does not embody patentable subject matter as defined in 35 USC 101.

See, e.g., *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974); *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Brothers Seed. Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948); *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 4-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *L. fermentum*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 12 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001

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of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 4-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing in the recitation of "log 3", "log 5" and the absence of "degrees" regarding temperatures.

In claim 1 under (e) the period intended by "stable" is not defined. Is it a few seconds, a few hours, days, weeks, months, years?

In claim 1, the recitation under (f) is confusing, since the connection between adhesion and inhibition of pathogens is unclear.

Claims 4-15 are vague, indefinite and incomplete in depending on a cancelled claim. In claim 4 the antecedent basis for "and a pharmaceutically acceptable carrier" is unclear. Does it modify the variant and component or only the component?

Moreover, in claims 1 and 4, the recitation of "component" renders the claims indefinite since this term is not defined with sufficient particularity. A "component" includes any lipid, any carbohydrate, any amino acid, any protein, water, CO₂, and various other organic and inorganic compounds and/or compositions.

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Claim 6 is confusing in the recitation of "a resistant starch". The "resistance" aspect is not defined with any particularity. Claim 7 is confusing in the language "high amylose starch". It is unclear what is intended by this terminology. Amylose is a component of starch. Claim 7 lacks antecedent basis in claim 6 for "high amylose starch".

Claims 10 and 12-13 are confusing in the recitation of "in the form of... a food product". It is apparent that the composition is a food product.

Claims 4 and 8-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend on another multiple dependent claim.. See MPEP § 608.01(n).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 8-10, 12, 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heinemann *et al.* (FEMS Microbiology Letters, 2000, vol. 190, "Purification and characterization of a surface-binding protein from

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Lactobacillus Fermentum RC-14 that inhibits adhesion of *Enterococcus faecalis* 1131", pages 177-80.)

The claims are drawn to an *L. fermentum* strain, and components thereof, which has certain properties, including the inhibition of pathogens.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., Abstract, since it similarly inhibits pathogens. The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or components thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. A "component" includes any lipid, any carbohydrate, any amino acid, any protein, water, CO₂, and various other organic and inorganic compounds and/or compositions. Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-2, 4-5, 8-10 and 12-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mikelsaar *et al.* (WO03/002131).

The claims are drawn to an *L. fermentum* strain, and components thereof, which has certain properties, including the inhibition of pathogens.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., pages 7 and 9, Tables, as well as page 8, lines 20-22), since it similarly inhibits pathogens and triggers immune modulation through anti-oxidative effects. The referenced microorganism appears to be identical to the presently claimed strain and is

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considered to anticipate the claimed microorganism or components thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. A "component" includes any lipid, any carbohydrate, any amino acid, any protein, water, CO₂, and various other organic and inorganic compounds and/or compositions. Consequently, the claimed strain and components thereof appear to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-2, 4-5, 8-10, 12, 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Plant *et al.* (Clinical and Diagnostic Laboratory Immunology, Mar. 2001, vol. 8, pages 320-324.)

The claims are drawn to an *L. fermentum* strain, and components thereof, which has certain properties, including adhesion to Peyer Patches.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., Table 2 since adheres to Peyer Patches). The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or components thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. A "component" includes any lipid, any carbohydrate, any amino acid, any protein, water, CO₂, and various other organic and inorganic compounds and/or compositions. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that

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which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 1-2, 4-5, 8-10, 12, 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blomberg *et al.* (Applied and Environmental Microbiology, 1993, vol. 59(1), "Inhibition of Adhesion of *Escherichia coli* K88 to Piglet Ileal Mucus by *Lactobacillus* spp.", pages 34-39.)

The claims are drawn to an *L. fermentum* strain, and a component thereof, which has certain properties, including antimicrobial effects.

The cited reference discloses a *L. fermentum* which appears to be identical to the presently claimed strain (see, e.g., page 39 since it has antimicrobial effects). The referenced microorganism appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism or a component thereof since it is of the same species as that of the microorganism claimed and is taught to be effective against the same types of pathogens. A "component" includes any lipid, any carbohydrate, any amino acid, any protein, water, CO₂, and various other organic and inorganic compounds and/or compositions. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

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Claims 1-2 and 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinemann *et al.* taken with Mikelsaar *et al.*, and Paul *et al.*

The Heinemann *et al.* and Mikelsaar *et al.* are discussed *supra*

The references differ from the invention as claimed in that the addition of a prebiotic such as a gum or a beta glucan is not disclosed and in the provision of tablets. However, Paul *et al.* adequately demonstrate that the administration of *L. fermentum* in conjunction with prebiotics such as oligosaccharides, inulin or beta-glucans is old and well known in the art (See, e.g., col. 9, lines 27-34). The provision of various formulations is disclosed at col. 15, lines 65 et seq.. The "agglomerated" material is deemed to substantially constitute a tablet.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the *L. fermentum* compositions of Heinemann *et al.* and/or Mikelsaar *et al.* by providing them in conjunction with additives other than in liquid dairy formulations, such as oligosaccharides, inulin or beta-glucans for their well known properties of containing fiber and essential nutrients and in a dried form, such as tablets, as suggested by the teachings of by Paul *et al.* for the expected benefit of providing *L. fermentum* compositions providing dietary fiber and essential nutrients in a formulation that are stable and easy to administer.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx
Primary Examiner
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